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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/785,532 01/17/97 GRAY

023070-06891

EXAMINER

HM21/1016

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ART UNIT 15 PAPER NUMBER

1642
DATE MAILED:

10/16/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on 3/13/98 papers #10 & 7/30/98 paper #13
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 26-40, 48-63 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 26-40, 48-63 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a):
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Art Unit: 1642

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

RESTRICTION

Applicant adds new claims 48-63 which are related to claims 26-40, and are not new matters.

Applicant's election with traverse of group I (claims 26-40, and 48-63), species B, sequences that hybridizes to the claimed sequences, and for species of sequences, SEQ ID No:9, in Paper No.13 is acknowledged. The traversal is on the ground(s) that the claims can be examined without undue burden for the Examiner. Furthermore, applicant recites that there is no legal authority to impose a restriction requirement on a single claim, even if the claims presents multiple independently patentable invention. Applicant recites In re Weber, Soder and Boksay, wherein " the discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim---no matter how broad, which means no matter how many independently patentable inventions may fall within it". This is not found persuasive because In re Weber, Soder and Boksay could not be applied in this instant application. The

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examiner does not refuse to examine the broad generic claim. The generic claim was only included in different independent patentable inventions, which are clearly distinct in objectives, method steps, reagents, dosages and schedules used, response variables, and criteria for success.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 26-40, and 48-63 are being examined.

The following rejections are withdrawn: 1) Rejection under 35 uSC 112, second paragraph of claims 26-41, in view of applicant's amendment.

The following are the remaining rejections.

REJECTION UNDER 35 USC 102

Rejection under 35 USC 102 of claim 26 pertaining to anticipation by Morris et al remains for reasons already of record in paper No.7. This rejection applies to claims 56, 61-63 as well.

Applicant argues that Morris et al discloses genes from a chromosomal translocation involving chromosomes 9 and 22. Thus there is no motivation to use these sequences to detect increased copy number at 20q13.2

Applicant's arguments set forth in paper No.10 have been considered but are not deemed to be persuasive for the following reasons:

This is a 102 rejection, and thus a motivation is not necessary. Similar to this instant application, Morris et al also teach a method for screening cancer, by contacting a nucleic acid

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sample from a human patient with a probe. Furthermore, the probe taught by Morris et al would inherently hybridize to the claimed SEQ IDNo:9 from 20q13.2 under stringent conditions, because the probe taught by Morris et al is 88% similar to the claimed SEQ ID No:9, under MPSRCH search. Any increase in copy number at 20q13.2 is thus would be inherently detected by said hybridization. Furthermore, the probe taught by Morris et al is also labeled for in situ hybridization, and the sample is a human chromosome sample.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH, NEW REJECTION

Claims 26-40, and 48-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is indefinite because it is not clear “an increased copy number” of what sequence is meant.

REJECTION UNDER 35 USC 102, NEW REJECTION

Claims 26, 56, 61-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Stokke et al, US 5,633,365.

Claims 26, 56, and 61-63 are drawn to a method of screening neoplastic cells comprising contacting a sample from a human patient with a probe which hybridizes under stringent conditions to a target polynucleotide sequence of SEQ ID No:9 from 20q13.2, and determining

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the presence or absence of increased copy number at 20q13.2. The specification further recites that said chromosome abnormality is at about position Flpter 0.825 on human chromosome 20 (20q13.2).

Stokke et al teach a method for detection of an amplification at about position Flpter 0.825 on human chromosome 20 , using probes which are specific to said region (the entire document, and especially table 2). Thus the chromosomal target region taught by Stokke et al is the same as the claimed invention. Furthermore, the method taught by Stokke et al is the same as the claimed invention because the probes taught by Stokke et al would encompass nucleotide sequences that hybridize to the claimed SEQ ID No:9. Moreover, the probe taught by Stokke et al is also labeled for in situ hybridization.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE OF ENABLEMENT

ClaimS 26-40, 48-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for screening breast cancer, does not reasonably provide enablement for a method for screening any neoplastic cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. .

Claim 26 is drawn to a method for screening neoplastic cells comprising hybridizing a nucleic acid sample from a human patient, using a probe which hybridizes under stringent conditions to SEQ ID NO:9 from the chromosome 20q13.2. The specification however only

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discloses an example of detecting breast cancer by hybridizing a nucleic acid sample from a human patient, using a probe which hybridizes under stringent conditions to SEQ ID NO:9 from the chromosome 20q13.2. The specification also describes that in the same 20q13 band, amplification was found in ovarian, bladder and colorectal tumor. However, because the area of the 20q13 band in the chromosome 20 is large, spanning several kb, and thus possibly several gene sequences, the claimed sequence SEQ ID No:9, which consists of only 2kb, is not necessary within the area associated with ovarian, bladder and colorectal tumor. As disclosed in the specification, p. 20, the isolated clones span about at least 600 kb. Yet the specification does not teach how to detect ovarian or bladder or colorectal tumor, using the claimed sequence SEQ ID No:9 as a probe. Furthermore, screening for neoplastic cells reads on screening for any types of cancer. Yet it is well known in the art, not all types of cancer are associated with abnormality of the chromosome 20q13.2. For example, Gray, JW et al, EP 0 430 402 A2 teach that chronic myelogenous leukemia is associated with abnormalities of chromosome regions 9q34 and 22q11 (p.45).

In the absence of sufficient correlation between one example of a method of detecting breast cancer described in the specification, and a method of detecting any type of cancer, and in view of the above contradiction, one of skill in the art would be forced into undue experimentation in order to use the claimed sequence SEQ ID No:9 to detect any type of cancer.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 7:00am to 3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2297. The fax phone number for this Group is (703) 308-4227.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [lila.feisee@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless **the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122**. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

October 1, 1998


LILA FEISEE
SUPERVISORY PATENT EXAMINER